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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,981

11/14/2003

Susan B. Roberts

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7590

01/05/2005

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/713,981

Applicant(s)

ROBERTS ET AL.

Examiner

Christopher J Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 61-91 and 95-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 61-91 and 95-97 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. The Preliminary Amendment filed 14 November 2003 has been received and entered in full.

### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 61, 62, 64, 65, 67, 68, 70, 72, 73, drawn to a method for isolating  $\gamma$ -secretase, a protein complex having  $\gamma$ -secretase activity, and a protein complex comprising  $\gamma$ -secretase, classified in class 435, subclass 183, for example.
  - II. Claims 63, 66, 69, 71, drawn to a molecule and a protein complex having  $\gamma$ -secretase activity, classified in class 530, subclass 300, for example.
  - III. Claims 74, 75, 81, drawn to an isolated functionally active substrate which is cleaved by  $\gamma$ -secretase, classification dependent upon substrate structure.
  - IV. Claims 76-79, drawn to a method for cleaving a functionally active substrate, classified in class 435, subclass 68.1, for example.
  - V. Claims 80, 82, 83, 84, 85, 86, drawn to a method for isolating a functionally-active  $\gamma$ -secretase substrate, classified in class 435, subclass 183, for example.
  - VI. Claims 87-91 and 95, drawn to a method for identifying an agent of interest that inhibits  $\gamma$ -secretase, classified in class 435, subclass 7.1, for example.
  - VII. Claim 96, drawn to a method for isolating an integral membrane protein, classified in class 530, subclass 350, for example.

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VIII. Claim 97, drawn to an integral membrane protein, classified in class 530, subclass 350, for example.

3. The inventions are distinct, each from the other because of the following reasons:

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons.

5. Inventions II, III, and VIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

6. Although the molecule of Invention II can be used to isolate the substrate of Invention III it is independent and distinct because it can be used in materially different methods such as a therapeutic or as a diagnostic. The molecule of Invention II is independent and distinct from the integral membrane protein of Invention VIII because it is not required to make or use the molecule/protein of Invention I.

7. Further, the substrate of Invention III can be prepared by processes which are materially different from molecule of Invention II, such as by chemical synthesis, or by isolation and purification from natural sources thus making it independent and distinct. The substrate of Invention III is independent and distinct from the integral membrane protein of Invention VIII because it is not required to make or use the substrate of Invention III.

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The integral membrane protein of Invention VIII is independent and distinct from the molecule of Invention II and the substrate of Invention II because neither of these Inventions is required to make or use the substrate of Invention III.

8. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, IV, V, VI, and VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of isolating  $\gamma$ -secretase, which is not required by any of the other Inventions. Invention IV requires search and consideration of cleaving a functionally active substrate, which is not required by any of the other Inventions. Invention V requires search and consideration of isolating a functionally-active  $\gamma$ -secretase substrate, which is not required by any of the other Inventions. Invention VI requires search and consideration of identifying an agent of interest that inhibits  $\gamma$ -secretase, which is not required by any of the other Inventions. Invention VII requires search and consideration of isolating an integral membrane protein, which is not required by any of the other Inventions.

9. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention II can be made through materially different methods such as chemical synthesis.

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10. Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention III can be used in materially different method such as a therapeutic.

11. Inventions VIII and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and I are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention I do not recite the use or production of the integral membrane protein of Invention VIII.

12. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II can be used in materially different method such as a therapeutic.

13. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the product of Invention III can be used in materially different method such as a therapeutic.

14. Inventions VIII and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and IV are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention IV do not recite the use or production of the integral membrane protein of Invention VIII.

15. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II can be used in materially different method such as a therapeutic.

16. Inventions V and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention III can be made through materially different methods such as chemical synthesis.

17. Inventions VIII and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and V are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention V do not recite the use or production of the integral membrane protein of Invention VIII.

18. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II can be used in materially different method such as a therapeutic.

19. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention III can be used in materially different method such as a therapeutic.

20. Inventions VIII and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and VI are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention VI do not recite the use or production of the integral membrane protein of Invention VIII.



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21. Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and VII are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention VII do not recite the use or production of the molecule of Invention II.

22. Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and VII are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention VII do not recite the use or production of the substrate of Invention III.

23. Inventions VII and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the integral membrane protein can be made through materially different processes such as by chemical synthesis.

24. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend**

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**from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

25. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

26. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

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27. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

28. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

29. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

January 3, 2005

A handwritten signature in black ink, appearing to read "Nichols", with a large, stylized loop at the end.